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| 10/743,975 | 12/23/2003 | Elena K. Davydova | EPICEN-09587 | 9377 |
| 72960 | 7590 | 05/25/2010 | | |
| Casimir Jones, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562 | | | EXAMINER BERTAGNA, ANGELA MARIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/743,975

Applicant(s)

DAVYDOVA ET AL.

Examiner

Angela M. Bertagna

Art Unit

1637

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

1. Applicant's response filed on March 10, 2010 is acknowledged. Claim 93 is currently pending. As discussed in greater detail in the "Response to Arguments" section, Applicant's arguments filed on March 10, 2010 have been fully considered and were persuasive in part. Any previously made objections or rejections not reiterated below have been withdrawn as being obviated by Applicant's response filed on March 10, 2010. However, since Applicant's response was not sufficient to overcome all of the previously made rejections and objections, this Office Action is made **FINAL**.

Correction of Inventorship

2. In view of the papers filed on March 10, 2010, it has been found that this non-provisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the deletion of Gary Dahl, Svetlana Gerdes, and Jerome Jendrisak and the addition of Krystyna Maria Kazmierczak. The correct inventorship is: Elena Davydova, Lucia Rothman-Denes, and Krystyna Maria Kazmierczak.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Drawings

3. The drawings are objected to, because Figure 1 contains a nucleic acid sequence that is greater than ten nucleotides in length that has not been identified by the appropriate SEQ ID NO either in the drawing or in the "Brief Description of the Drawings" section. See 37 CFR 1.821(b) and MPEP 2422.02

If Applicant elects to insert the required sequence identifier into Figure 1, Applicant is reminded that any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The use of trademarks, specifically MONOQ (see pages 71 and 170) and LOOP-AMP (see page 91), has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 93 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 7,452,705. Although the conflicting claims are not identical, they are not patentably distinct from each other, because it would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to practice the method of claim 93 using the compositions recited in claims 1-16 of the '705 patent. Also, the method recited in claims 17-27 of the '705 patent suggests the method of the instant claim 93.

The instant claim 93 is drawn to a method for making RNA that comprises combining a single-stranded DNA oligonucleotide having an N4 virion RNA polymerase promoter sequence with an N4 virion RNA polymerase, specifically mini-vRNAP or the Y678F mutant form of mini-vRNAP, and incubating the resulting mixture under conditions effective to allow RNA synthesis.

Claims 1-5 and 13-16 of the '705 patent are drawn to isolated nucleic acids that encode mini-vRNAP or the Y678F mutant form of the N4 virion RNA polymerase. Claims 6-11 of the '705 patent are drawn to isolated recombinant host cells containing one of the nucleic acids of claim 1. Claim 12 of the '705 patent is drawn to a recombinant vector that comprises a DNA segment that encodes N4 mini-vRNAP or the Y678F mutant form of N4 mini-vRNAP. Claims 17-27 of the '705 patent are drawn to a method of making a full-length N4 vRNAP or N4 mini-vRNAP.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to use the N4 mini-vRNAP or Y678F mutant form N4 mini-vRNAP recited in the claims of the '705 patent to practice the method of making RNA recited in the instant claim 93. Since claims 1-27 of the '705 patent teach that the recited nucleic acid products encode an N4

mini-vRNAP or a Y678F mutant form of mini-vRNAP, an ordinary artisan would have been motivated to use the RNA polymerase encoded by the products of claims 1-5 and 13-16, produced by the products of claims 6-12, or produced by the methods of claims 17-27 for its intended purpose (RNA synthesis) with a reasonable expectation of success. As noted in MPEP 2144.07, it is *prima facie* obvious to utilize a known material for its intended purpose in the absence of unexpected results. In this case, the ordinary artisan would have recognized from the teachings of the claims of the '705 patent that the recited N4 mini-vRNAP or Y678F mini-vRNAP was suitable for use in a method of making RNA that comprises combining a single-stranded DNA oligonucleotide having an N4 virion RNA polymerase promoter sequence with either N4 mini-vRNAP or the Y678F mutant form of N4 mini-vRNAP and incubating the resulting mixture under conditions effective to allow RNA synthesis. It is also noted that no evidence of unexpected results has been presented. Further, it is noted that the instant application is a continuation-in-part of the application that issued as the '705 patent, and, therefore, the protections of 35 U.S.C. 121 do not apply. Thus, the method of the instant claim 93 is *prima facie* obvious in view of claims 1-27 of the '705 patent.

Terminal Disclaimer

7. The terminal disclaimer filed on March 10, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Serial No. 10/719,372 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer filed on March 10, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 7,452,705 has been reviewed and is NOT accepted. In particular, the terminal disclaimer was not signed by all owners (*i.e.*, Epicentre Technologies and the University of Chicago) and, therefore, supplemental terminal disclaimers are required from the remaining owners. See also the "Terminal Disclaimer Informal Checklist" that is present in the electronic application file and dated 4/22/2010.

Response to Arguments

8. Applicant's arguments filed on March 10, 2010 have been fully considered, and they were persuasive, in part.

Regarding the objection to Figures 1 and 2, Applicant states that the "Brief Description of the Drawings" section has been amended to include the appropriate sequence identifiers (see page 7). This argument was persuasive with respect to Figure 2, and, accordingly, the objection has been withdrawn. However, this argument was not persuasive with respect to Figure 1, because the brief description of this figure has not been amended to include a sequence identifier. Accordingly, the objection to Figure 1 has been maintained.

Regarding the previously made objections to the specification, Applicant states that the amendment obviates all of the previously made objections (pages 7-8). This argument was persuasive, and accordingly, the objections have been withdrawn. It is noted, though, that the trademarks MonoQ and Loop-Amp are not properly recited (see above).

Regarding the previously made rejections on the ground of obviousness-type double patenting citing US Patent No. 7,452,705 and copending Application Serial No. 10/719,372, Applicant argues that the terminal disclaimers submitted on March 10, 2010 have obviated the rejections (see page 8). This argument was persuasive with respect to the provisional rejection made citing the '372 application, and, accordingly, the provisional rejection has been withdrawn. This argument was not persuasive with respect to the rejection made citing the '705 patent, however. As noted above, the terminal disclaimer for the '705 patent was not approved, and, therefore, the rejection has been maintained.

Conclusion

9. No claims are currently allowable. It is noted that claim 93 is free of the art, but it has rejected for other reasons, specifically on the ground of obviousness-type double patenting.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela M Bertagna/
Examiner, Art Unit 1637

/Young J Kim/
Primary Examiner, Art Unit 1637